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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,276	02/29/2000	Marc R. Montminy	SALK1650-2	1983

7590

05/01/2002

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EXAMINER

WORTMAN, DONNA C

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/515,276

Applicant(s)

MONTMINY, MARC R.

Examiner

Donna C. Wortman, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 4/17/02 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☐ The proposed amendment(s) will not be entered because:  
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): Please see attached.  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: please see attached.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-7, 12, 17.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
10. ☐ Other: \_\_\_\_\_

Donna C. Wortman, Ph.D.  
Primary Examiner  
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The amendment to claim 6 has been entered and overcomes the rejection previously made under 35 USC 112, second paragraph, which is withdrawn.

With respect to the rejection of claims 1-7, 12 and 17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record, Applicant has again argued (1) that the Examiner has required the art to demonstrate that Applicant's [invention's] method of action for treating diabetes was known; (2) that the fact that the method of action of Applicant's invention is not discussed in the Merck Manual is not relevant to the question of enablement; (3) that the Mayr and Herzig references, previously cited by Applicant, do not support the rejection; (4) that the rejection of record does not provide scientific reasoning for why Applicant's method is not enabled; and (5) that the facts of record, including the description in the specification of methods to identify compounds that inhibit the interaction of CREB and CBP, a general description of routes of administration, e.g., and the Mayr and Herzig articles, are sufficient to overcome the rejection.

These arguments have been considered but not found persuasive essentially for reasons already of record. In point (1), above, Applicant has misstated the Examiner's position, as the Merck Manual was cited only to help establish the state of the prior art with respect to diabetes treatment, since determination of enablement as of the filing date involves, *inter alia*, consideration of the state of the prior art. Such determination of the state of the prior art is also relevant to Applicant's point (2). With reference to

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points (3), (4), and (5), while the Mayr and the Herzig articles provide some indication that the CREB:CBP interaction may be relevant to some aspects of diabetes, they also support the unpredictability inherent in field, since even though they were published well after the effective filing date of the instant application, they do not provide factual evidence that administering a compound that inhibits binding of CREB to CBP to an individual with diabetes mellitus has therapeutic benefit; instead, the articles indicate that this is an area that invites further experimentation. Also with respect to points (4) and (5), while it is so that there is no *per se* requirement to provide human clinical data in order to enable a method of therapy, the presence or absence of working examples in the specification as filed is appropriately considered, and Applicant's specification provides no basis for correlating the identification of compounds identified by the disclosed *in vitro* screening method with a treatment method for diabetes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.  
Primary Examiner  
Art Unit 1648

dcw  
April 30, 2002